

Survey: **NBS4/18**  
month: **October 2018**  
Participant-No: **9900667**  
date of issue: **13.10.18**



Referenzinstitut für Bioanalytik

Tijen Tanyalcin MD,PH  
Tanyalcin Tip laboratuvari  
Kizilkanat Sag lik Sitisi B Blok kat 1  
1359 sokak no 4/3  
35220 ALSANCAK, IZMIR  
TURKEY



Survey directors

Prof. Dr. C. Knabbe  
Prof. Dr. Dr. K.P. Kohse  
Prof. Dr. M. Neumaier

Head of RfB

Dr. W. J. Geilenkeuser  
Dr. A. Kessler

Bonn, 31. October 2018

## Certificate

We confirm that you have participated in the survey for neonatal screening.

You have met the requirements of the survey for the following analytes:

TSH (2) | 17-OH-progesterone (2)

**This certificate is valid until the end of April 2019.**

The number in parentheses characterizes the analytical method used.

The assignment of the number to the respective method and/or the respective instrument is to be taken from the total evaluation.

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Dr. A. Kessler

Bonn, 31. October 2018

## Participation certificate

We confirm that you have participated in the survey for neonatal screening.

The analytes determined by you are as follows:

TSH (2) | 17-OH-progesterone (2) | IRT (2)

The number in parentheses characterizes the analytical method used.  
The assignment of the number to the respective method and/or the respective instrument is to be taken from the total evaluation.

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Listing and Evaluation of all your results

**Explanations**

**Certificate**

A certificate is issued (given) for an analyte only if the basis for an evaluation of the accuracy is given by the guidelines of the German Medical Association and/or if an evaluation is possible in analogy to these guidelines (see comments on the evaluation) and, if both results for an analyte are within the given acceptance limits. (marked as '+' below C)

**Certificate of participation**

In the participation certificate all analytes which are included in the list on this page are listed.  
 If all analytes are listed on the certificate no participation certificate is printed.

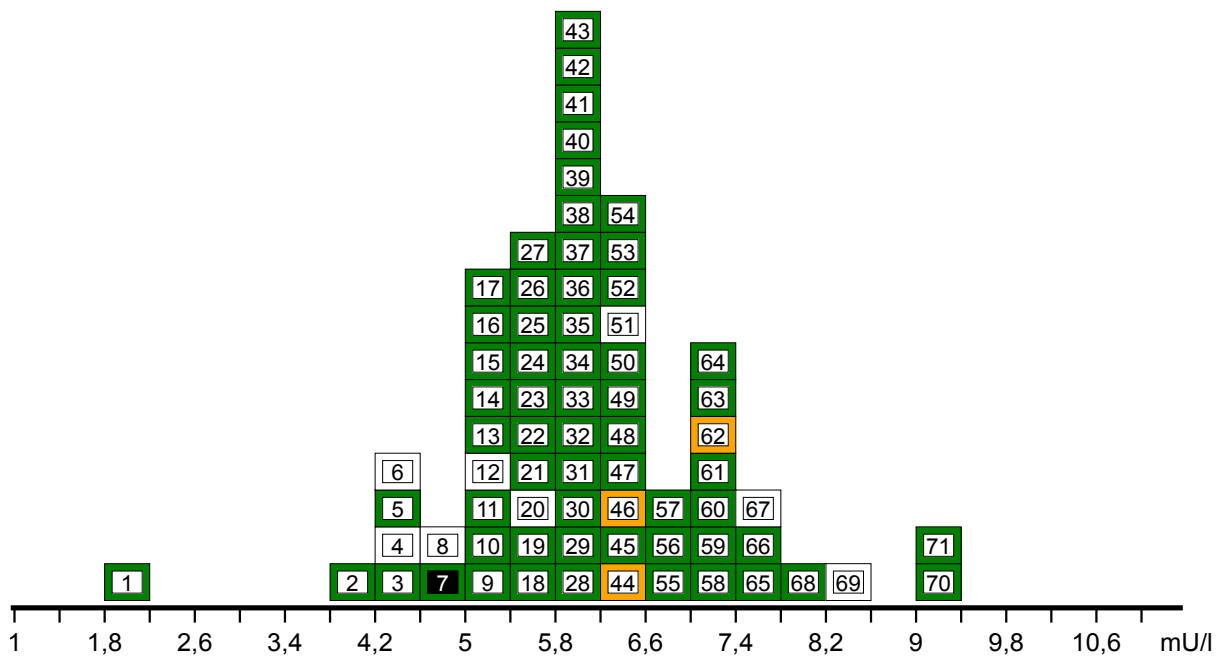
Legend:	C=Certification, M=No of method, R=your result, D=difference (R-T) Dmax= maximum allowable amount of difference in measurement, partly given by annex 1 of the guideline of the BÄK (Dt. Ärzteblatt 111, Heft 38, 19.9.2014). T = target value, either reference method value or assigned value, LL   UL = lower resp. upper limit	Certification: + = fulfilled ( quotient   D/Dmax   <= 1.0 ) - = not fulfilled (quotient   D/Dmax   > 1.0) ± = certification cancelled because of technical and/or analytical reasons
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	C	M	R	D/Dmax	T	LL	UL							
TSH [mU/l]	+	2	A 4.70 B 22.5	0.07 -0.25	4.51 24.3	2.11 17.0	6.91 31.6							
17-OH-progesterone [nmol/l]	+	2	A 54.9 B 20.8	0.25 0.31	51.0 19.0	35.7 13.3	66.3 24.7							
IRT [µg/l]	±	2	A 53.9 B 15.1	-0.65 2.26	67.0 9.00	46.9 6.30	87.1 11.7							

Findings NBS4/18 -October 2018-  
Neonatal - Screening, TSH, Sample A  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">r n</span> <span style="border: 1px solid orange; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="border: 1px solid black; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications		Statistics of Implications, related to Classifications			
	normal	CH/AGS/CF possible	none	new card	plasma sample	other
N = 71	60	3	57	1		
XM= 6,0 mU/l				3		
SD= 1,1 mU/l						
CV= 19,0 %						

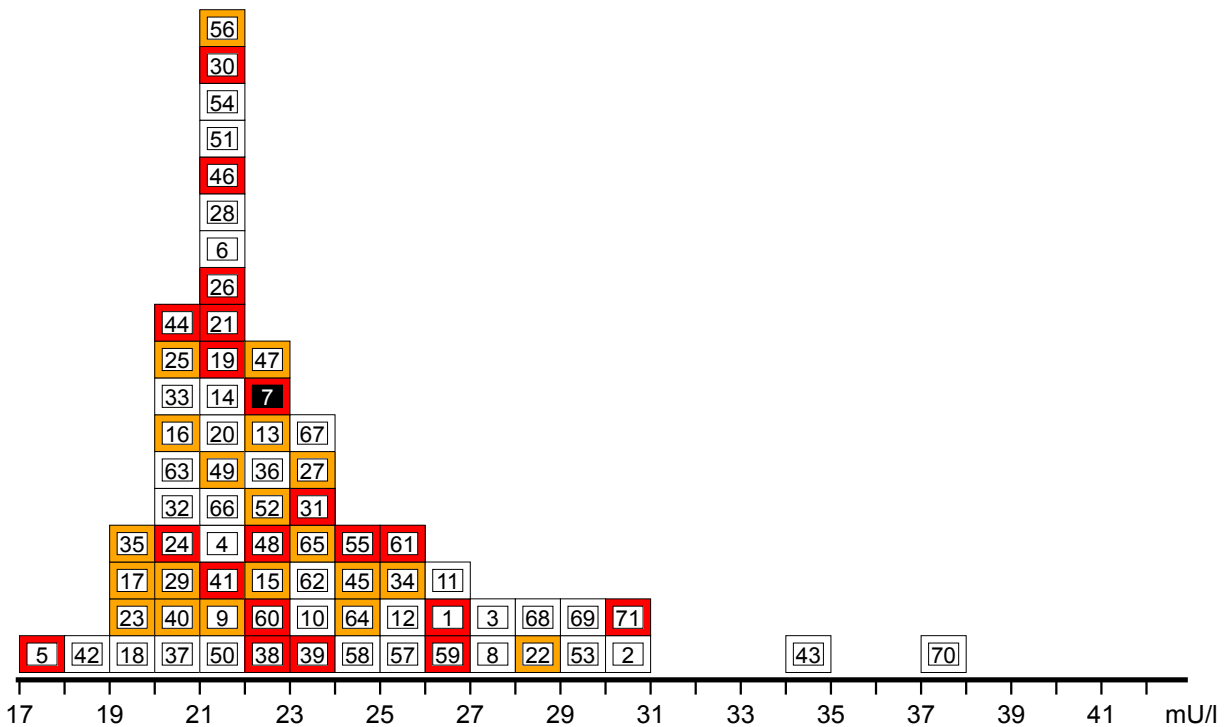
**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications								
								2	4	6	8	10	normal	CH/AGS/CF possible	CH/AGS/CF evident	other
All Kits		71	1.90	5.08	<b>5.99</b>	7.02	9.05						60	3	0	0
2	9	2	1.90		<b>3.11</b>		4.31						1	0	0	0
2	99	2	4.70		<b>4.75</b>		4.80		•				1	0	0	0
3	350	2	6.40		<b>7.70</b>		9.00						1	0	0	0
4	91	2	5.47		<b>5.94</b>		6.40						1	0	0	0
4	99	2	6.80		<b>7.25</b>		7.70						2	0	0	0
4	245	20	4.50	5.24	<b>5.80</b>	6.33	6.70						20	0	0	0
4	246	9	5.20	5.44	<b>6.20</b>	7.32	7.50						8	1	0	0
4	247	18	5.00	5.52	<b>6.20</b>	7.10	8.10						16	2	0	0
5	77	8	4.10	4.17	<b>5.08</b>	5.86	6.14						7	0	0	0
5	111	2	8.50		<b>8.78</b>		9.05						1	0	0	0

Other Kits: 1 77(1),3 99(1),3 245(1),3 247(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:  $\frac{M}{\text{mu}}$   $\frac{\text{Mu}}$  is: -21.54 % -1.0 %

<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="border: 1px solid green; padding: 2px;">r n</span> <span style="border: 1px solid orange; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="border: 1px solid red; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: black;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 71	■ normal				
XM= 23,2 mU/l	■ CH/AGS/CF possible 20		17	3	
SD= 3,6 mU/l	■ CH/AGS/CF evident 20			18	1
CV= 15,5 %	■ other				

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications								
								10	20	30	40	Green	Orange	Red	Black	
All Kits		71	17.0	20.2	<b>22.0</b>	26.2	37.8						0	20	20	0
2	9	2	21.1		<b>23.6</b>		26.1						0	0	1	0
2	99	2	22.5		<b>24.8</b>		27.0		•				0	0	1	0
3	350	2	21.8		<b>29.8</b>		37.8						0	0	0	0
4	91	2	21.0		<b>21.2</b>		21.3						0	0	0	0
4	99	2	21.1		<b>23.1</b>		25.1						0	0	0	0
4	245	20	17.0	19.7	<b>21.3</b>	23.1	24.9			+			0	9	7	0
4	246	9	20.1	20.6	<b>22.0</b>	23.8	24.6			+			0	4	4	0
4	247	18	18.8	20.0	<b>21.9</b>	26.0	28.7			+			0	6	6	0
5	77	8	21.4	22.2	<b>26.8</b>	32.4	34.1			+			0	1	0	0
5	111	2	29.9		<b>30.1</b>		30.2			+			0	0	1	0

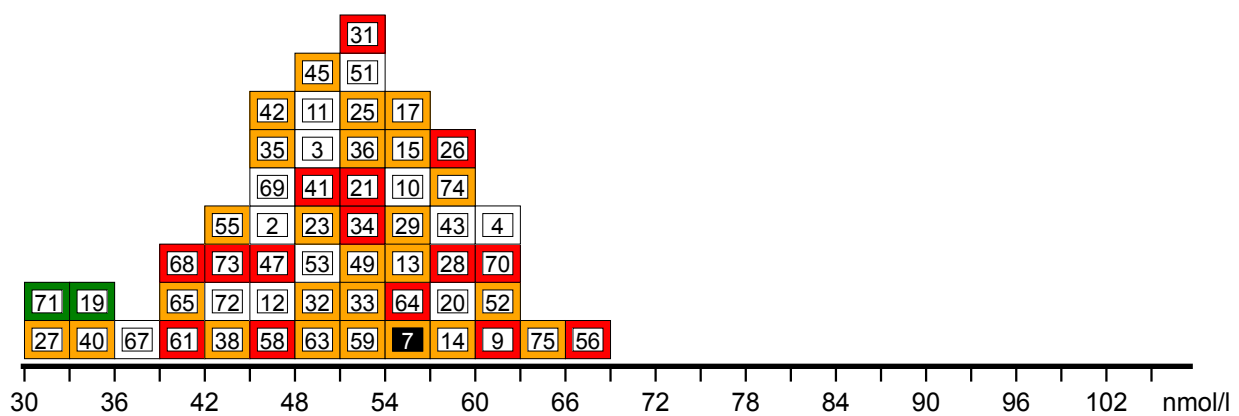
Other Kits: 1 77(1),3 99(1),3 245(1),3 247(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:	M	Mu
	2.2 %	-9.0 %

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Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 55	<span style="color: green;">■</span> normal 2	1			
XM= 50,4 nmol/l	<span style="color: orange;">■</span> CH/AGS/CF possible 25		22	1	2
SD= 8,0 nmol/l	<span style="color: red;">■</span> CH/AGS/CF evident 15		7	8	
CV= 15,9 %	other 1		1		

**Kit Evaluation for Sample A**

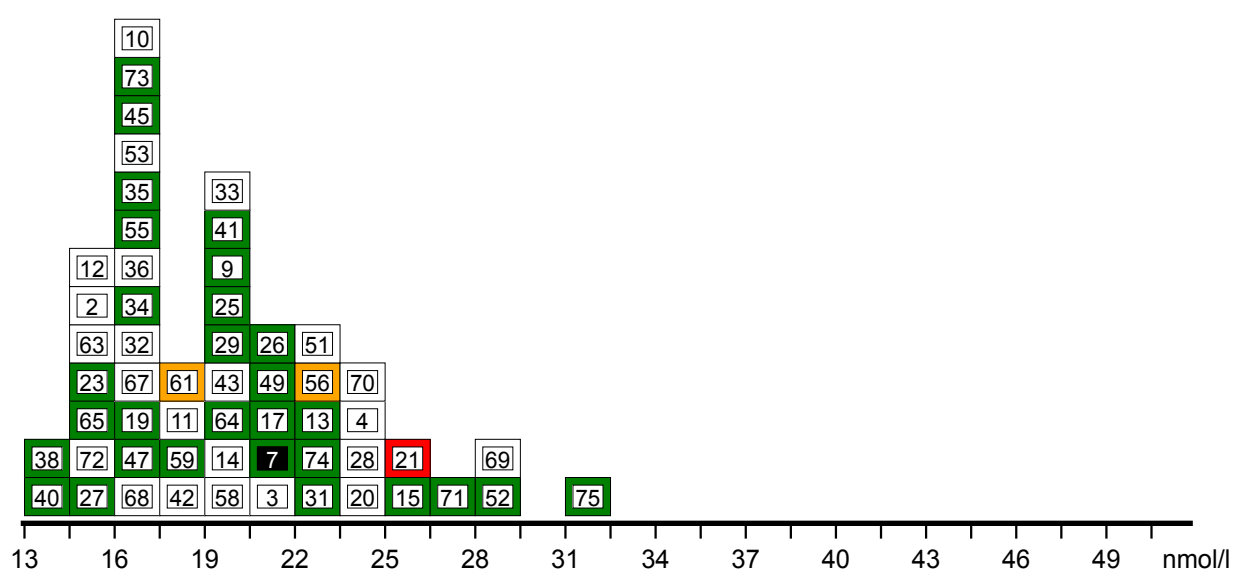
M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications									
								0	20	40	60	80	100	Green	Orange	Red	White
All Kits	55	30.7	42.9	<b>51.0</b>	59.4	68.9		—+—						2	25	15	1
3	350	2	53.1	<b>56.9</b>		60.6								0	0	1	0
4	245	20	46.2	48.7	<b>52.5</b>	59.8	68.9	+—						0	10	3	1
4	246	8	30.7	35.4	<b>54.1</b>	58.1	59.8	—+—						0	4	4	0
4	247	17	35.0	39.9	<b>46.4</b>	51.1	60.0	+—						1	9	6	0
5	111	2	30.8		<b>38.7</b>		46.6							1	0	0	0

Other Kits: 2 9(1),2 99(1),3 245(1),3 247(1),4 91(1),6 99(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:

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Neonatal - Screening, 17-OHP, Sample B  
Participant No 9900667

<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
	XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 55	<span style="color: green;">■</span> normal 29	28			
XM= 19,7 nmol/l	<span style="color: orange;">■</span> CH/AGS/CF possible 2		2		
SD = 3,9 nmol/l	<span style="color: red;">■</span> CH/AGS/CF evident 1		1		
CV = 20,2 %	other				

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max	Kit Classifications								
								0	10	20	30	40	<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	<span style="background-color: black; color: white;">■</span>
All Kits		55	13.0	16.0	<b>19.0</b>	23.9	31.0					29	2	1	0	
3	350	2	23.0		<b>24.0</b>		24.9					0	0	0	0	
4	245	20	15.9	17.2	<b>19.9</b>	24.8	31.0					8	1	1	0	
4	246	8	14.7	15.1	<b>19.4</b>	24.1	25.6					8	0	0	0	
4	247	17	13.0	14.9	<b>16.6</b>	18.9	20.0					10	1	0	0	
5	111	2	26.5		<b>27.7</b>		28.9					1	0	0	0	

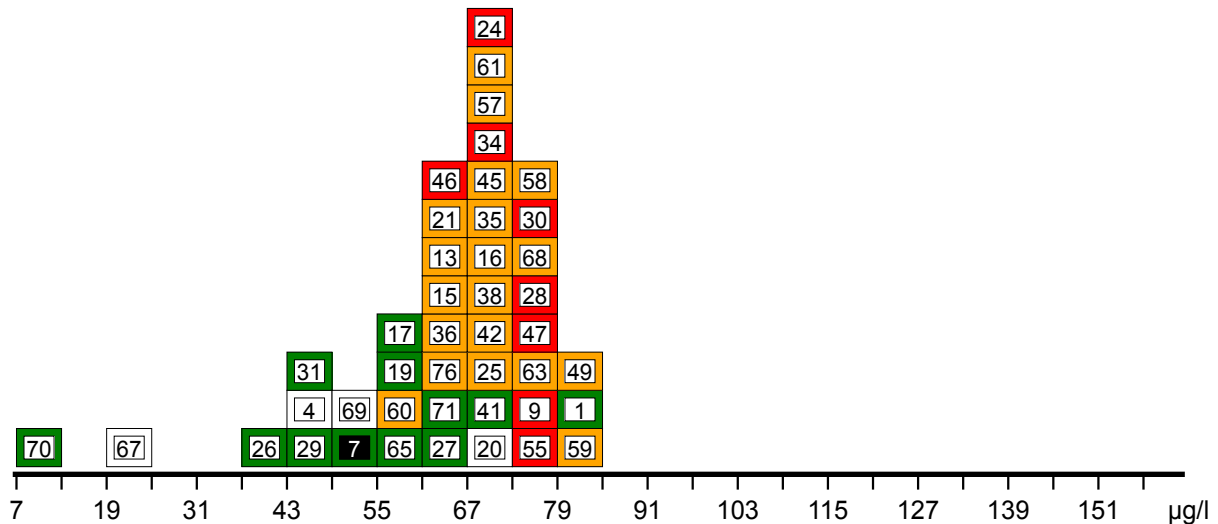
Other Kits: 2 9(1),2 99(1),3 245(1),3 247(1),4 91(1),6 99(1),

The deviation of your result from the total median M	M	Mu
and from the median of the corresponding sub-collective (kit) Mu is:		

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Neonatal - Screening, IRT, Sample A  
Participant No 9900667



<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 43	<span style="color: green;">■</span> normal 12	10			1
XM= 63,9 µg/l	<span style="color: orange;">■</span> CH/AGS/CF possible 19		7		12
SD = 14,8 µg/l	<span style="color: red;">■</span> CH/AGS/CF evident 8		1		7
CV = 23,1 %	other				

**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max		20	40	60	80	100	120	Kit Classifications			
															<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	<span style="color: black;">■</span>
All Kits	43	7.80	54.0	<b>67.0</b>	75.8	82.3					—+—				12	19	8	0
2	52	2	53.9		<b>67.7</b>		81.5			•					2	0	0	0
4	91	2	67.0		<b>69.6</b>		72.2								0	1	0	0
4	245	14	55.4	61.1	<b>66.5</b>	74.6	82.3				—+—				4	8	2	0
4	246	5	42.2		<b>46.4</b>		65.0								3	2	0	0
4	247	14	59.6	67.1	<b>73.3</b>	76.6	79.0				—+—				1	8	5	0
5	111	2	54.6		<b>59.1</b>		63.5								1	0	0	0

Other Kits: 2 9(1),3 245(1),3 247(1),3 350(1),

The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is: -19.49 % -20.35 %

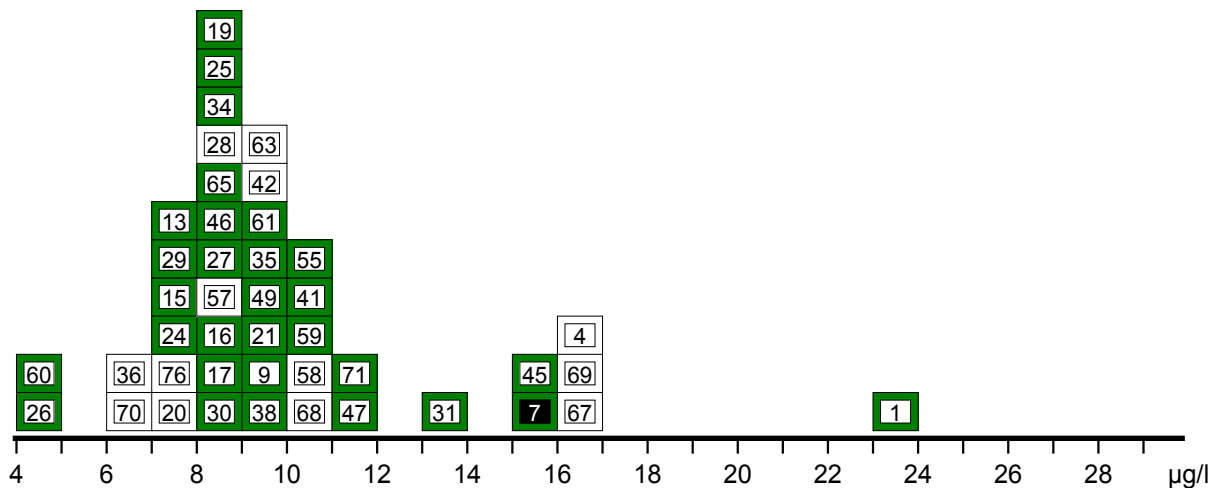


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Participant No 9900667



**Legend:**

N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
CV = coefficient of variation		CF = cystic fibrosis
M = method number		<span style="background-color: black; color: white; padding: 2px;">r n</span> = marks your result box



**Descriptive Statistics**

N = 43  
XM= 9,8 µg/l  
SD = 3,5 µg/l  
CV = 36,5 %

**Statistics of classifications**

■ normal 30  
■ CH/AGS/CF possible  
■ CH/AGS/CF evident  
other

**Statistics of Implications, related to Classifications**

none 29    new card    plasma sample    other

**Kit Evaluation for Sample B**

M	Kit	N	Min	16.P	50.P	84.P	Max		5	10	15	20	25	Kit Classifications			
														■	■	■	■
All Kits	43	4.10	7.35	<b>9.00</b>	13.5	23.2								30	0	0	0
2	52	2	15.1		<b>19.2</b>		23.2				●			2	0	0	0
4	91	2	7.00		<b>7.60</b>		8.20							0	0	0	0
4	245	14	6.80	7.26	<b>8.15</b>	9.70	15.5							12	0	0	0
4	246	5	4.10		<b>7.60</b>		13.6							5	0	0	0
4	247	14	8.30	8.78	<b>9.45</b>	10.1	11.2							10	0	0	0
5	111	2	11.9		<b>14.3</b>		16.6							1	0	0	0

Other Kits: 2 9(1),3 245(1),3 247(1),3 350(1),

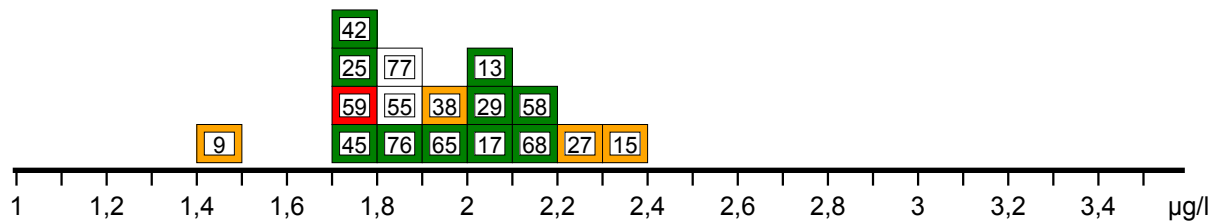
The deviation of your result from the total median M and from the median of the corresponding sub-collective (kit) Mu is:	M	Mu
	67 %	-21.15 %

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Participant No 9900667



**Legend:**

N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	= 16. bis 84. percentile with median
XM = mean value		CH = congenital hypothyroidism
SD = standard deviation	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	AGS = adrenogen. syndrome
CV = coefficient of variation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	CF = cystic fibrosis
M = method number		<span style="background-color: black; border: 1px solid black; padding: 2px;">r n</span> = marks your result box



Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 17	<span style="color: green;">■</span> normal 10	10			
XM= 1,8 µg/l	<span style="color: orange;">■</span> CH/AGS/CF possible 4		1		3
SD= 0,2 µg/l	<span style="color: red;">■</span> CH/AGS/CF evident 1				1
CV= 11,8 %	other				

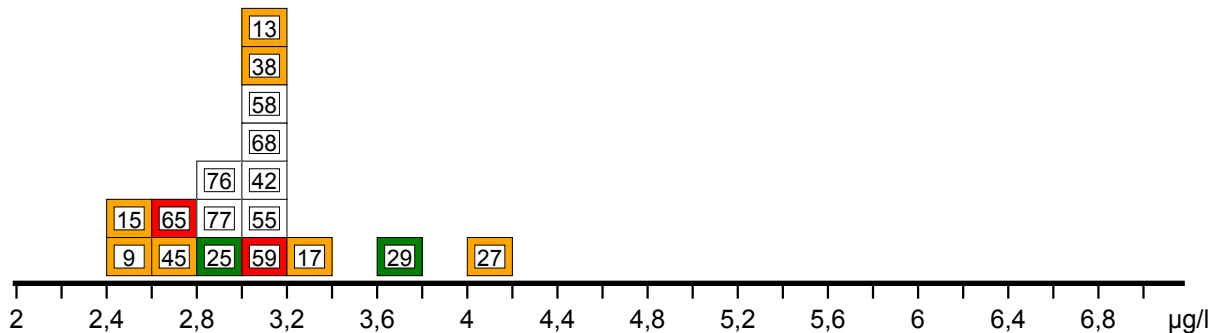
**Kit Evaluation for Sample A**

M	Kit	N	Min	16.P	50.P	84.P	Max				Kit Classifications				
								0,7	1,4	2,1	2,8	<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	
All Kits	17	17	1.40	1.70	<b>1.90</b>	2.11	2.33					10	4	1	0
2	255	3	1.70		<b>1.70</b>		2.00					3	0	0	0
4	255	14	1.40	1.72	<b>1.90</b>	2.16	2.33					7	4	1	0

Other Kits:

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<b>Legend:</b>	N = number of results	<span style="border: 1px solid black; padding: 2px;">r n</span> = result box/result code no.	—+— = 16. bis 84. percentile with median
	XM = mean value	<span style="background-color: green; border: 1px solid black; padding: 2px;">r n</span> <span style="background-color: orange; border: 1px solid black; padding: 2px;">r n</span> = normal   CH/AGS/CF possible	CH = congenital hypothyroidism
	SD = standard deviation	<span style="background-color: red; border: 1px solid black; padding: 2px;">r n</span> <span style="border: 1px solid black; padding: 2px;">r n</span> = CH/AGS/CF evident   other	AGS = adrenogen. syndrome
	CV = coefficient of variation		CF = cystic fibrosis
	M = method number		<span style="background-color: black; color: white; padding: 2px;">r n</span> = marks your result box

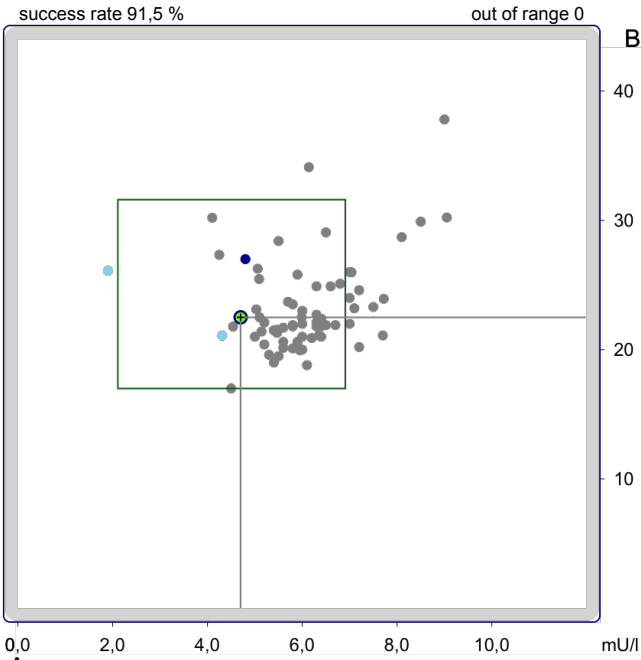


Descriptive Statistics	Statistics of classifications	Statistics of Implications, related to Classifications			
		none	new card	plasma sample	other
N = 17	<span style="color: green;">■</span> normal 2	2			
XM= 3,0 µg/l	<span style="color: orange;">■</span> CH/AGS/CF possible 7		1		6
SD= 0,3 µg/l	<span style="color: red;">■</span> CH/AGS/CF evident 2				2
CV= 13,1 %	other				

Kit Evaluation for Sample B																
M	Kit	N	Min	16.P	50.P	84.P	Max	1	2	3	4	5	Kit Classifications			
													<span style="color: green;">■</span>	<span style="color: orange;">■</span>	<span style="color: red;">■</span>	0
All Kits	17	2.40	2.59	<b>3.00</b>	3.26	4.00				—+—			2	7	2	0
2	255	3	2.60		<b>2.80</b>		3.20			I			1	2	0	0
4	255	14	2.40	2.59	<b>3.03</b>	3.48	4.00			—+—			1	5	2	0

Other Kits:

Analyte **TSH**  
Method all methods



No of participants	<b>71</b>	
sample/unit	A	mU/l B
mean	6.01	23.2
standard deviation	1.14	3.62
coefficient of variation	19.0	15.6

**Sample A [mU/l]**

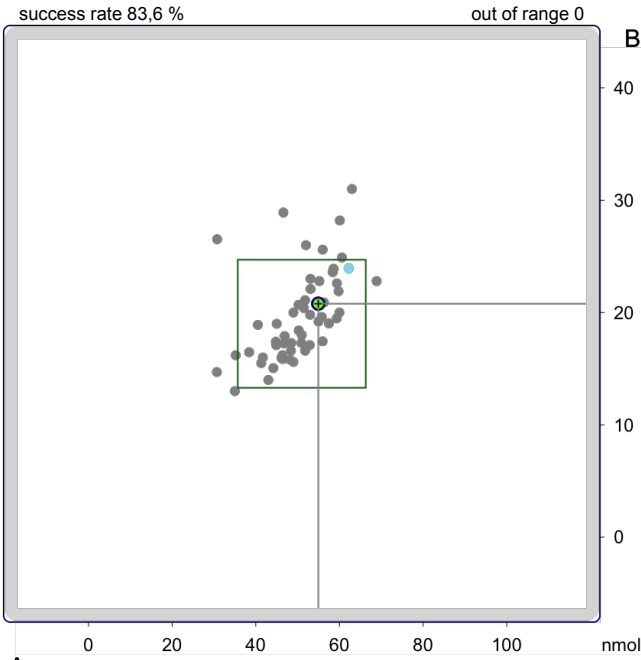
M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		71	1.90	5.08	5.99	7.02	9.05
4	245	20	4.50	5.24	5.80	6.33	6.70
4	246	9	5.20	5.44	6.20	7.32	7.50
4	247	18	5.00	5.52	6.20	7.10	8.10
5	77	8	4.10	4.17	5.08	5.86	6.14

**Sample B [mU/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		71	17.0	20.2	22.0	26.2	37.8
4	245	20	17.0	19.7	21.3	23.1	24.9
4	246	9	20.1	20.6	22.0	23.8	24.6
4	247	18	18.8	20.0	21.9	26.0	28.7
5	77	8	21.4	22.2	26.8	32.4	34.1

Other kits (number):  
1-77(1), 2-09(2), > 2-99(2)<, 3-99(1), 3-245(1), 3-247(1), 3-350(2), 4-91(2), 4-99(2), 5-111(2),

Analyte **17-OH-progesterone**  
Method all methods



No of participants	<b>55</b>	
sample/unit	A	nmol/l B
mean	50.5	19.7
standard deviation	8.08	3.99
coefficient of variation	16.0	20.2

**Sample A [nmol/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	30.7	42.9	51.0	59.4	68.9
4	245	20	46.2	48.7	52.5	59.8	68.9
4	246	8	30.7	35.4	54.1	58.1	59.8
4	247	17	35.0	39.9	46.4	51.1	60.0

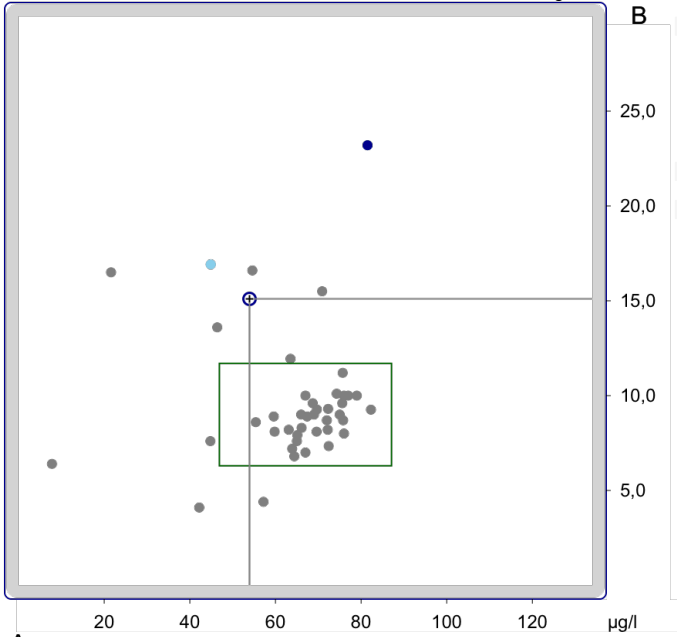
**Sample B [nmol/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		55	13.0	16.0	19.0	23.9	31.0
4	245	20	15.9	17.2	19.9	24.8	31.0
4	246	8	14.7	15.1	19.4	24.1	25.6
4	247	17	13.0	14.9	16.6	18.9	20.0

Other kits (number):  
2-09(1), > 2-99(1)<, 3-245(1), 3-247(1), 3-350(2), 4-91(1), 5-111(2), 6-99(1),

Analyte **IRT**  
Method all methods

success rate 72,0 % out of range 0



**Sample A [µg/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	7.80	54.0	67.0	75.8	82.3
4	245	14	55.4	61.1	66.5	74.6	82.3
4	246	5	42.2		46.4		65.0
4	247	14	59.6	67.1	73.3	76.6	79.0

**Sample B [µg/l]**

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		43	4.10	7.35	9.00	13.5	23.2
4	245	14	6.80	7.26	8.15	9.70	15.5
4	246	5	4.10		7.60		13.6
4	247	14	8.30	8.78	9.45	10.1	11.2

Other kits (number):  
2-09(1), >2-52(2)<, 3-245(1), 3-247(1), 3-350(1), 4-91(2), 5-111(2).

No of participants	<b>43</b>	
sample/unit	A	B
mean	64.0	9.85
standard deviation	14.8	3.60
coefficient of variation	23.2	36.5